

2556. Misbranding of Cloro devices. U. S. v. 5 * * *. F. D. C. No. 23629.
Sample Nos. 82720-H, 82721-H.)

LIBEL FILED: August 14, 1947, District of Montana.

ALLEGED SHIPMENT: On or about April 23 and May 7, 1947, by the L. P. Dickey Co., from Tucson, Ariz.

PRODUCT: 5 Cloro devices at Butte, Mont. Examination showed that the devices were electrical, and that when charged and operated in accordance with the directions furnished, they would give off chlorine gas and vapors of eucalyptol.

LABEL, IN PART: "Cloro Reg." and "Roh Company Tucson Arizona."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the devices failed to bear adequate directions for use.

DISPOSITION: October 13, 1947. Default decree of condemnation. It was ordered that the devices be turned over to the Montana State School of Mines, to be disassembled and the component units thereof to be used for scientific and experimental purposes.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

2557. Adulteration of dextrose in distilled water. U. S. v. 28 Bottles * * *.
(F. D. C. No. 25391. Sample No. 6387-K.)

LIBEL FILED: August 17, 1948, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about March 17 and May 12, 1947, from Cleveland, Ohio.

PRODUCT: 28 bottles of *dextrose in distilled water* at Pittsburgh, Pa. The product was in hermetically sealed flasks and was intended for intravenous injection.

NATURE OF CHARGE: The article was adulterated while held for sale after shipment in interstate commerce under Section 501 (b), in that it purported to be and was represented as "Dextrose Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and the quality and purity of the article fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: September 9, 1948. Default decree of condemnation and destruction.

2558. Adulteration of dextrose in distilled water. U. S. v. 30 Flasks * * *.
(F. D. C. No. 25453. Sample No. 4838-K.)

LIBEL FILED: August 13, 1948, District of Massachusetts.

ALLEGED SHIPMENT: On or about October 28, 1946, from Cleveland, Ohio.

PRODUCT: 30 flasks of *dextrose in distilled water* at Worcester, Mass. The product was in hermetically sealed flasks and was intended for intravenous injection.

LABEL, IN PART: "Dextrose 10% W/V in Distilled Water 1000 cc."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Dextrose Injection," the name of which is recognized in the United States Pharmacopoeia, and its quality and purity fell below the official standard since the standard provides that injections must be substan-

*See also No. 2596.

tially free of undissolved material, whereas the article was contaminated with undissolved material. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: September 27, 1948. Default decree of condemnation and destruction.

2559. Adulteration and misbranding of dextrose solution and adulteration of sodium chloride solution. U. S. v. 330 Flasks, etc. (F. D. C. No. 25095. Sample Nos. 18071-K, 18073-K.)

LIBEL FILED: July 20, 1948, Southern District of Indiana.

ALLEGED SHIPMENT: During the period of March 14, 1947, to March 8, 1948, by the Continental Pharmacal Co., from Cleveland, Ohio.

PRODUCT: 330 flasks of *dextrose solution* and 36 flasks of *sodium chloride solution* at Indianapolis, Ind.

LABEL, IN PART: "Dextrose 5% in Isotonic Solution of Sodium Chloride 500 cc. * * * sterile and nonpyrogenic" and "Isotonic Solution of Sodium Chloride U. S. P. 500 cc."

NATURE OF CHARGE: Adulteration, Section 501 (b), the articles purported to be and were represented as "Dextrose and Sodium Chloride Injection" and "Sterile Isotonic Sodium Chloride Solution for Parenteral Use," respectively, drugs the names of which are recognized in the United States Pharmacopoeia, an official compendium, and their quality and purity fell below the official standards since the articles were contaminated with undissolved material; and the *dextrose solution* was contaminated with living micro-organisms and pyrogen.

Misbranding, Section 502 (a), the statement "This product is sterile and non-pyrogenic" on the label of the *dextrose solution* was false and misleading.

DISPOSITION: September 24, 1948. Default decree of forfeiture and destruction.

2560. Adulteration and misbranding of dextrose in isotonic solution of sodium chloride. U. S. v. 14 Flasks * * *. (F. D. C. No. 25357. Sample Nos. 6696-K, 6708-K.)

LIBEL FILED: August 11, 1948, Western District of New York.

ALLEGED SHIPMENT: On or about June 3, 1947, by the Continental Pharmacal Co., from Cleveland, Ohio.

PRODUCT: 14 flasks of *dextrose in isotonic solution of sodium chloride* at Gowanda, N. Y. The solution was contained in hermetically sealed flasks and was intended for intravenous injection. That intravenous use was contemplated was evidenced by the statement on the flask label "For the purpose of filling and rinsing the tubing this unit contains 50 cc in excess of the declared volume * * * Single dose container."

LABEL, IN PART: "Dextrose 5% In Isotonic Solution of Sodium Chloride 1000 cc * * * sterile and non-pyrogenic."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Dextrose Injection in Isotonic Sodium Chloride Solution," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and the quality and purity of the article fell below the official standard since it was contaminated with living micro-organisms and contained pyrogen.